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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/682,371

10/09/2003

Randy Westlund

GUID.077PA

6103

51294 7590 05/28/2009  
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EXAMINER

ALTER, ALYSSA MARGO

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/28/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                        |  |
|------------------------------|--------------------------------------|----------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/682,371 | <b>Applicant(s)</b><br>WESTLUND ET AL. |  |
|                              | <b>Examiner</b><br>Alyssa M. Alter   | <b>Art Unit</b><br>3762                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 67-74 is/are pending in the application.
- 4a) Of the above claim(s) 67-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 1-4, 7-14, 16-18 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois et al. (US 5,716,392). Bourgeois et al. discloses gaining access to the patient pericardium through the patients chest proximate a cardiac chamber, see figure 6, and delivering myocardium penetrating components, needle 53 and strand 55 as seen in figure 7. Bourgeois et al. additionally provides a lead possessing an electrode (depicted as 59 in figures 9-10) that is advanced into the myocardium via the needle and strand. Bourgeois et al. teaches the device substantially as claimed but fails to teach placing the lead over the strand and needle. It would have been obvious to one having ordinary skill in the art at the time the invention was made

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to modify the needle and strand dragging the lead to the desired location by placing the lead over the needle and strand at the desired location in the myocardium. Such a modification would provide the predictable results preventing the weakening or breaking of the strand when pulling the lead during implantation.

Additionally, such a modification could also provide the predictable results of reducing or eliminating the need for the second trocar 81 and forceps 83 to anchor the lead and remove the needle, which would simplify the implantation of the lead as well as reduce the access sites in the patient's chest. Such a reduction of access sites would reduce the amount of trauma sustained by the patient.

As to claims 7, "In the present embodiment it is contemplated MCRD 92 would feature a drug to elute a steroid, such as the sodium phosphate of dexamethasone" col. 7, lines 18-21.

As to claims 9-11 and 16-17, Bourgeois et al. discloses that a helix 56 may be included on strand 55. "Helix 56 functions to assist in fixing electrode 59 within tissue, as is well known in the art, without (or with) the use of crimp clip 90" col. 6, lines 17-19. Therefore, the examiner considers Bourgeois et al. to disclose a helical mechanism as an active fixation mechanism for affixing the electrode in the myocardium.

As to claim 15, Bourgeois et al. discloses the claimed invention except for the suture fixation element. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the fixation element as taught by Bourgeois et al. with a suture to provide the predictable results of affixing the electrode

to the myocardium. Furthermore, it was known in the art at the time the invention was made to employ sutures as attachment means for implantable medical devices.

As to claim 19, Bourgeois et al. discloses in col. 5, lines 60-63, "As seen in FIG. 13 needle 53 essentially has two portions; a first curved portion 54 and a second straight portion 56. In the preferred embodiment first curved portion 54 has a radius of curvature "R" of 13 mm over 30 degrees". Therefore the examiner considers the shallow angle to be about 30 degrees which is between the range of 5 and 45 degrees. Furthermore, Bourgeois et al. discloses in col. 6, lines 4-7, the "length of strand 55 and type of needle 53 permit the lead of the preferred embodiment to be introduced using only a 10 mm trocar, Thus only an incision of 10 mm long would need to be made to insert the lead.

In the alternative, although the examiner considers Bourgeois et al. to disclose a shallow angle between 5 and 45 degrees above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the shallow angle, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233 (see MPEP 2144.05).

2. Claims 5-6 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Bourgeois et al. (US 5,716,392) as applied to claims 1-4, 7-14, 16-18 and 20-22 above. The modified Bourgeois et al. discloses the device substantially as claimed except for the dilator or dilating sheath. It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert a dilator or

dilating sheath to create space within the myocardium in order to provide the predictable results of easier implantation and maneuverability of the needle and lead to reduce the amount of tissue trauma sustained by the patient during implantation. Furthermore, it is additionally well known in the art to employ dilators or dilating sheaths.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

/Alyssa M Alter/  
Examiner  
Art Unit 3762